K002488

JAN - 5 2001

Attachment 3

Summary of Safety and Efficacy Summary of Kelo-cote™ Topical Gel

Manufacturer:	Advanced Bio-Technologies, Inc. PO Box 3099, Silverdale, WA 98383
Regulatory Affairs Contact:	David Bryant
Telephone:	011 44 1477 549392
Date Summary Prepared:	August 8, 2000
Device Trade Name:	Kelo-cote™ Topical Gel
Common or Usual Name:	Silicone Gel
Classification:	Currently unclassified by FDA.
Description:	Kelo-cote™ topical gel is a self drying, topical gel made from medical grade silicone. The primary function of the dressing is to aid in the management of both existing and new hypertrophic and keloid scarring on scars resulting from burns, general surgical procedures and trauma wounds The Advanced Bio-Technologies Inc, Kelo-cote™ topical gel comes in a 15 gram tube for easy application. The gel is supplied non-sterile.
Intended Use:	Kelo-cote™ topical gel is intended for the management of old and new hypertrophic and keloid scarring on scars resulting from burns, general surgical procedures and trauma wounds. Discontinue use if any infection of the wound is suspected and seek guidance from a health care professional. Not for use on third degree burns. Not to be used on open wounds. Not for patients with dermatological conditions which disrupt the integrity of the skin in areas of coverage.
Substantial Equivalence:	Substantial equivalence was provided in 510(k)'s Spenco Silicone Gel Sheet,Spenco Medical Corp and Novagel® Silicone Gel Sheeting, Brennen Medical Inc.
Testing Summary:	.All tests performed in accordance with ISO10993-1 show the product to be non toxic and harmless for its intended application.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 5 2001

Advanced Bio-Technologies, Inc.
c/o Mr. David Bryant
Cranage HealthCare International
53 Needham Drive, Suite 5
Cranage
Cheshire, United Kingdom
CW4 8FB

Re: K002488
Trade Name: Kelo-cote™ Topical Gel
Regulatory Class: Unclassified
Product Code: MDA
Dated: November 15, 2000
Received: November 22, 2000

Dear Mr. Bryant:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Miriam C. Provost for

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K002488

510(k) Number (if known): K002488

Device name: Kelo-cote™ Topical Gel

Indications For Use:

Kelo-cote™ topical gel is intended for OTC use for the management of:

Old and new hypertrophic and keloid scarring on scars resulting from burns, general surgical procedures and trauma wounds.

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ **OR Over The Counter Use** ✓
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Miriam C. Provost for C. Witten
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002488